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**UNITED STATES DISTRICT COURT
 CENTRAL DISTRICT OF CALIFORNIA**

**CHRISTINA CORRELL, INDIVIDUALLY
 AND AS GUARDIAN AD LITEM TO J.C.,
 MINOR**

Plaintiff(s),

v.

**CVS Health Corporation and Rite Aid
 Corporation,**

Defendants.

Civil Action No.:

COMPLAINT & JURY DEMAND

DEMAND FOR JURY TRIAL

PLAINTIFF'S ORIGINAL COMPLAINT AND JURY DEMAND

Plaintiff Christina Correll individually and as representative of J.C., a minor, pursuant to Fed. R. Civ. P. 17(c)(1)(A), by and through their undersigned counsel, bring this Complaint for damages against Defendants CVS Health Corporation and Rite Aid Corporation, (hereinafter, "Defendants") and in support, state the following:

1. This is an action brought on behalf of Plaintiffs, Christina Correll (hereinafter, "Plaintiff Mother"), the natural and general guardian and mother of J.C. (hereinafter, "Plaintiff Child"), a minor, arising out of the failure of Defendants to warn about the dangers of prenatal exposure to Paracetamol, also known as Acetaminophen (hereinafter "APAP"). As a result, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

2. Defendants entirely failed their duty to adequately warn of the hazards of prenatal exposure to APAP, which was a direct and proximate cause of Plaintiffs' injuries and

1 associated damages.

2 **STATEMENT OF PARTIES**

3 3. At all material times Plaintiffs have been citizens and residents of Los Angeles
4 County, California.

5 4. CVS Health Corporation, is incorporated in Delaware.

6 5. Rite Aid Corporation, is incorporated in Pennsylvania.

7 6. CVS Health Corporation, is involved in the research, development, testing,
8 manufacture, labeling, production, marketing, promotion, and/or sale of APAP through its over-
9 the-counter store brand, Acetaminophen (hereinafter, the “APAP Products”).

10 7. Rite Aid Corporation, is involved in the research, development, testing,
11 manufacture, labeling, production, marketing, promotion, and/or sale of APAP through its over-
12 the-counter store brand, Acetaminophen (hereinafter, the “APAP Products”).

13 8. CVS Health Corporation, is individually, and jointly and severally liable to
14 Plaintiffs for damages they suffered, arising from Defendants’ design, manufacture, marketing,
15 labeling, distribution, sale, and placement of the defective APAP Products into the market,
16 effectuated directly and indirectly through its agents, servants, employees, and/or owners, all
17 acting within the course and scope of its agencies, services, employments, and/or ownership.

18 9. Rite Aid Corporation, is individually, and jointly and severally liable to Plaintiffs
19 for damages they suffered, arising from Defendants’ design, manufacture, marketing, labeling,
20 distribution, sale, and placement of the defective APAP Products into the market, effectuated
21 directly and indirectly through its agents, servants, employees, and/or owners, all acting within
22 the course and scope of its agencies, services, employments, and/or ownership.

23 10. CVS Health Corporation, is vicariously liable for the acts and/or omissions of its
24 employees and/or agents, who were at all material times acting on behalf of CVS Health
25 Corporation, and within the scope of its employment or agency.

26 11. Rite Aid Corporation, is vicariously liable for the acts and/or omissions of its
27 employees and/or agents, who were at all material times acting on behalf of Rite Aid
28 Corporation, and within the scope of its employment or agency.

JURISDICTION and VENUE

12. This Court has subject-matter jurisdiction under 28 U.S.C. § 1332(a), based on complete diversity of citizenship between Plaintiffs and Defendants. *See supra* ¶¶ 3–4.

13. The amount in controversy exceeds \$75,000.

14. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the events or omissions giving rise to Plaintiffs’ claims occurred in this judicial district.

15. Defendants have conducted and continue to conduct substantial business in the State of California and in this District, distribute the APAP Products in this District, receive substantial compensation and profits from sales of the APAP Products in this District, and have made material omissions and misrepresentations and breaches of warranties in this District and caused injuries in this District to Plaintiffs, among others, so as to subject Defendants to in personam jurisdiction in this District. It was foreseeable at all times that Defendants could be haled into court in the State of California for its conduct that caused injuries to citizens of California, like Plaintiffs in this action. An exercise of in personam jurisdiction by this Court over Defendants comports fully with due process and does not offend traditional notions of fair play and substantial justice.

16. Defendants are registered to transact business in California.

FACTS COMMON TO ALL COUNTS

APAP Is Marketed as the Safe Pain Reliever for Pregnant Women, but APAP Can Cause

ASD/ADHD in Children

17. APAP is widely used by pregnant women to relieve pain or discomfort during the term of their pregnancy.

18. APAP was initially discovered in the late 1800’s.

19. APAP was introduced to the US market in 1955 as the first aspirin-free pain reliever. APAP was originally marketed and sold as a product to reduce fever in children, packaged like a red fire truck with the slogan, “for little hotheads.”

20. Billions of units of APAP are sold annually in North America alone.

1 21. APAP has long been marketed as the safest, and the *only* appropriate, over-the-
2 counter pain relief drug on the market for pregnant women.

3 22. Forty to 65% of pregnant women in the United States use APAP during
4 pregnancy.

5 23. Based upon information and belief, a majority of women who use APAP during
6 pregnancy do so electively for the treatment of headaches, muscle pain, back pain, and
7 discomfort.

8 24. These pregnant women electively choose to take APAP because Defendants have
9 marketed APAP as a safe pain reliever for pregnant women.

10 25. However, scientific and epidemiological research shows that prenatal exposure
11 to APAP alters fetal development significantly increasing the risks of neurodevelopmental
12 disorders, including but not limited to, autism spectrum disorder (“ASD”) and attention-
13 deficit/hyperactivity disorder (“ADHD”).

14 26. Undisturbed development of the human brain in utero is vital to the health and
15 wellness of a child’s development. The human brain is vulnerable and extremely sensitive in
16 utero. During this sensitive time-period in utero, certain chemicals have been found to cause
17 permanent brain injury at low exposure levels.

18 27. Once ingested by the mother, APAP is known to readily cross the placenta and
19 blood-brain barrier.

20 28. ASD is a serious neurological and developmental disorder that affects how
21 people interact with others, communicate, learn, and behave.

22 29. There are three functional levels of ASD, with Level 1 requiring support with
23 activities of daily living, Level 2 requiring substantial support with activities of daily living, and
24 Level 3 requiring very substantial support with activities of daily living.

25 30. Treatments for ASD include behavioral management therapy, cognitive behavior
26 therapy, joint attention therapies, medications, occupational therapy, physical therapy, social
27 skill training, and speech-language therapy. Treatment for ASD lasts a lifetime, as there is no
28 cure.

1 31. ADHD is a chronic neurodevelopmental disorder resulting in attention difficulty,
2 hyperactivity, and impulsiveness.

3 32. ADHD begins in childhood and persists through adulthood. ADHD contributes
4 to low self-esteem, troubled relationships, and difficulty with school, work, and familial
5 relationships.

6 33. Treatments for ADHD, include, but are not limited to, chronic medication usage
7 and various therapies. Treatment for ADHD lasts a lifetime, as there is no cure.

8 34. In or around 2018, the Center for Disease Control and Prevention (“CDC”)
9 found that 1 in 44 (2.3%) 8-year-old children have been diagnosed with ASD.

10 35. This represents an increase from a prior CDC finding that 1 in 68 U.S. children
11 born in 2002 have ASD, which already represented a more than a 100% increase compared with
12 children born a decade prior.

13 36. As of 2019, 8.8% of children had been diagnosed with ADHD, or roughly
14 325,000 children per year.

15 37. Parental awareness and changes in diagnoses do not fully account for the rapid
16 rise in these diagnoses.

17 38. Rather, neurotoxic exposures, such as prenatal APAP exposure, partly explain a
18 trending increase in diagnoses.

19 39. For decades, beginning in 1987, the scientific community has published studies
20 showing that prenatal ingestion of APAP can cause ASD and ADHD.

21 40. A 2019 meta-analysis of studies from 1987 to 2016, with relative risks ranging
22 from 1.16 to 1.34, found statistically significant nineteen percent (19%) increased risk of ASD
23 in children whose mothers took APAP during pregnancy.

24 41. Since 2013, there have been six European birth cohort studies, examining over
25 70,000 mother-child pairs, showing the association between prenatal use of APAP and ASD and
26 ADHD, confirming the results of studies dating back to 1987.

27 42. The overall body of scientific evidence has shown for decades that prenatal use
28 of APAP can cause ASD and ADHD in the child.

1 43. During all relevant times herein, Defendants was engaged in the business of
2 manufacturing and selling the APAP Products in the United States, and the weight of the
3 scientific evidence available showed prenatal exposure to APAP significantly increases the risk
4 of neurodevelopmental disorders in children exposed to APAP prenatally, including but not
5 limited to ASD and ADHD.

6 44. At the time Plaintiff Mother was pregnant with Plaintiff Child the scientific
7 evidence regarding the risks of in utero exposure of APAP was available to Defendants, and
8 Defendants knew or should have known that prenatal use of APAP can cause ASD or ADHD.

9 45. Moreover, despite scientific evidence that prenatal use of APAP can cause ASD
10 or ADHD, Defendants continued and continue, to market APAP Products as safe pain relievers
11 for pregnant women, making mothers believe they are choosing a safe drug for even minor
12 aches, pains, and headaches.

13 **Plaintiff Mother Took APAP Products while Pregnant,**
14 **and It Caused ASD in Plaintiff Child**

15 46. Plaintiff Mother used APAP Products while she was pregnant with Plaintiff
16 Child.

17 47. Over the course of her pregnancy with Plaintiff Child, and during each trimester,
18 Plaintiff Mother took the APAP Products approximately three to seven times a day for body and
19 feet aches and pain relief.

20 48. Plaintiff Mother believed it was safe for her to take APAP Products during her
21 pregnancy.

22 49. Indeed, Plaintiff Mother was instructed by her health care provider(s) to not take
23 ibuprofen or aspirin while pregnant but was informed she could take APAP freely without risk
24 to Plaintiff Child.

25 50. There is no warning on the APAP Products' labels specifically addressing the
26 risks of ASD if a mother ingests APAP while pregnant.

27 51. Had Plaintiff Mother known of the risk of ASD in her child from taking APAP
28 while pregnant, she would not have taken the APAP Products.

1 52. Plaintiff Child was born on October 21, 2004.

2 53. Plaintiff Mother started to have concerns about Plaintiff Child's development
3 before he began school. Specifically, at that time, Plaintiff Child exhibited developmental
4 delays.

5 54. Plaintiff Child was diagnosed with autism when he was three years old in
6 approximately 2007 or 2008.

7 55. Plaintiff Child exhibits stimming behaviors in the form of repetitive, unusual
8 body movements and/or noises like clapping his hands, rocking, and kicking his feet.

9 56. Plaintiff Child receives in support services for speech therapy and often
10 repeatedly talks about the same subjects.

11 57. Plaintiff Child has received special services from his school for ASD since he
12 was five years old.

13 58. Plaintiff Child requires an immense amount of assistance to complete the normal
14 tasks of his daily life.

15 **ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS**

16 59. Due to Defendants' acts of fraudulent concealment, Defendants are estopped
17 from relying on any statutes of limitations or repose. Such acts include Defendants' intentional
18 concealment from Plaintiff Mother and the general public that APAP is defective when there is
19 prenatal exposure, while continuing to market the APAP Products with the adverse effects
20 described in this Complaint.

21 60. Given Defendants' affirmative actions of concealment by failing to disclose
22 information about the defects known to it but not the public—information over which
23 Defendants had exclusive control—and because Plaintiff Mother could not reasonably have
24 known that the APAP Products were defective, Defendants are estopped from relying on any
25 statutes of limitations that might otherwise be applicable to the claims asserted in this
26 Complaint.

27 61. Plaintiffs, in any event, commenced this action within two years of discovering
28 or having reason to discover their causes of action.

CLAIMS FOR RELIEF

COUNT I: STRICT LIABILITY – FAILURE TO WARN

62. Plaintiffs restate, reallege, and incorporate by reference the allegations set forth in the rest of this Complaint as if fully set forth herein.

63. At the time of Plaintiffs' injuries, the APAP Products were defective and unreasonably dangerous to foreseeable consumers using the APAP Products in a foreseeable manner during pregnancy, including Plaintiff Mother, because they lacked an adequate warning.

64. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, labeling, selling, distributing, and promoting the APAP Products, which were defective and unreasonably dangerous to consumers, including Plaintiff Mother, because they did not contain adequate warnings or instructions concerning the dangerous characteristics of ingesting APAP during pregnancy. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, labeled, promoted, and sold the APAP Products within this District and aimed the marketing at the ultimate consumer. Defendants was at all relevant times involved in the retail and promotion of the APAP Products marketed and sold in this District.

65. Defendants had a duty to warn of the risks associated with the use of the APAP products during pregnancy.

66. The APAP Products ingested by Plaintiff Mother during pregnancy were in the same or substantially similar condition as they were when they left possession of the Defendants.

67. Defendants expected and intended the APAP Products to reach users such as Plaintiff Mother in the condition in which the APAP Products were sold.

68. Plaintiff Mother did not materially alter the APAP Products prior to ingestion.

69. Plaintiff Mother ingested the APAP Products during pregnancy as indicated on the APAP Products' labels.

1 70. Plaintiff Mother was unaware of the defects and dangers of the APAP Products
2 during pregnancy and was specifically unaware that prenatal exposure increases the risk of brain
3 and behavioral development of children in utero.

4 71. The labels on the APAP Products to consumers lack any warning specific to
5 pregnant women. The information that Defendants did provide or communicate to consumers
6 failed to contain relevant warnings, hazards, and precautions that would have enabled
7 consumers such as Plaintiff Mother to utilize the products safely and with adequate protection
8 during pregnancy, or to decide to not use or ingest the APAP Products at all.

9 72. This alleged failure to warn is not limited to the information contained on the
10 APAP Products' labeling. Defendants were able, in accord with federal law, to comply with
11 relevant state law by disclosing the known risks associated with exposure to or use of APAP
12 during pregnancy through other non-labeling mediums, including, but not limited to, promotion,
13 advertisements, public service announcements, and/or public information sources. But
14 Defendants did not disclose these known risks through any medium.

15 73. At all relevant times, Defendants had a duty to properly test, develop, design,
16 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, and supply the
17 APAP Products; provide proper warnings for the APAP Products; and take such steps as
18 necessary to ensure the APAP Products did not cause users and consumers, and their children,
19 to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn
20 Plaintiff Mother of dangers associated with exposure to or use of APAP during pregnancy.
21 Defendants, as a manufacturer, seller, and/or distributor of pharmaceutical medication, is held to
22 the knowledge of an expert in the field.

23 74. At the time of manufacture, Defendants could have provided the warnings or
24 instructions regarding the full and complete risks of the APAP Products during pregnancy
25 because Defendants knew or should have known of the unreasonable risks of ASD and ADHD
26 associated with prenatal exposure to and/or the use of such products.

27 75. At all relevant times, Defendants failed and deliberately refused to investigate,
28 study, test, or promote the safety of the APAP Products, or to minimize the dangers to

1 consumers of the APAP Products and to those who would foreseeably use or be harmed by the
2 APAP Products, including Plaintiffs.

3 76. Defendants failed to adequately warn consumers, like Plaintiff Mother, about the
4 significant increased risk of neurodevelopmental disorders in children exposed to APAP
5 prenatally, including but not limited to ASD and ADHD.

6 77. Defendants failed to adequately inform reasonably foreseeable consumers, like
7 Plaintiff Mother, of the proper usage of the APAP Products.

8 78. Even though Defendants knew or should have known that APAP posed a grave
9 risk of harm to Plaintiff Child, Defendants failed to exercise reasonable care to warn of the
10 dangerous risks associated with use and prenatal exposure.

11 79. Plaintiff Mother was exposed to the APAP Products during pregnancy without
12 knowledge of their dangerous characteristics.

13 80. At all relevant times, Plaintiff Mother used and/or was exposed to the use of the
14 APAP Products while using them for their intended or reasonably foreseeable purposes during
15 pregnancy, without knowledge of their dangerous characteristics.

16 81. Plaintiff Mother could not have reasonably discovered the defects and risks
17 associated with the APAP Products prior to or at the time of Plaintiff consuming APAP during
18 pregnancy. Plaintiff Mother relied upon the skill, superior knowledge, and judgment of
19 Defendants to know about and disclose serious health risks associated with using the APAP
20 Products.

21 82. If Plaintiff Mother had been properly warned of the defects, dangers, and risks
22 associated with prenatal exposure to APAP, Plaintiff Mother would have decided to not ingest
23 the APAP Products at all. Defendants' failure to properly warn of those defects, dangers, and
24 risks associated with prenatal exposure to APAP was a substantial factor in causing Plaintiffs'
25 injuries and damages.

26 83. Defendants are liable to Plaintiffs for injuries caused by Defendants' negligent or
27 willful failure, as described above, to provide adequate warnings or other relevant information
28

1 and data regarding the appropriate use of the APAP Products and the risks associated with the
2 use of APAP.

3 84. As a direct and proximate result of Defendants placing defective APAP Products
4 into the stream of commerce, and Plaintiff Mother's foreseeable use and ingestion of the APAP
5 Products during pregnancy, Plaintiff Child was exposed to APAP prenatally, causing him to
6 develop ASD.

7 85. As a direct and proximate result of Defendants placing defective APAP Products
8 into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and
9 suffering, emotional distress, lost wages and earning capacity, and diminished quality of life.
10 Plaintiffs respectfully seek all damages to which they may be legally entitled.

11 **COUNT II: NEGLIGENCE**

12 86. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
13 set forth in the rest of this Complaint as if fully set forth herein.

14 87. Although Defendants had a duty to use reasonable care in testing, developing,
15 designing, manufacturing, marketing, labeling, selling, distributing, promoting, and preparing
16 written instructions and warnings for the APAP Products, Defendants failed to do so.

17 88. Defendants, directly or indirectly, caused the APAP Products to be sold,
18 distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff Mother. At all
19 relevant times, Defendants registered, researched, manufactured, distributed, marketed,
20 promoted, and sold the APAP Products within this district and aimed at a consumer market
21 within this district.

22 89. Defendants knew, or in the exercise of reasonable care should have known, that
23 the APAP Products were defectively and unreasonably designed and/or manufactured, and/or
24 marketed, and were unreasonably dangerous and likely to injure persons that were prenatally
25 exposed to them. Defendants knew or should have known that Plaintiff Mother was unaware of
26 the dangers and defects inherent in the APAP Products when she was ingesting them during her
27 pregnancy with Plaintiff Child.
28

1 90. At all relevant times, Defendants had a duty to exercise reasonable care in the
2 marketing, advertisement, promotion, and sale of the APAP Products. Defendants' duty of care
3 owed to consumers and the general public included providing accurate, true, and correct
4 information concerning the risks of using APAP during pregnancy and appropriate, complete,
5 and accurate warnings concerning the potential adverse effects of APAP and, in particular, the
6 significantly increased risk of causing neurodevelopmental disorders in children through
7 prenatal exposure to APAP.

8 91. At all relevant times, Defendants knew or, in the exercise of reasonable care,
9 should have known of the hazards and dangers of APAP ingestion while pregnant and,
10 specifically, the significantly increased risk of causing neurodevelopmental disorders in
11 children through prenatal exposure to APAP.

12 92. Defendants failed to provide any kind of warning to pregnant consumers, like
13 Plaintiff Mother, about the significantly increased risk of causing neurodevelopmental disorders
14 in children through prenatal exposure to APAP.

15 93. Accordingly, at all relevant times, Defendants knew or, in the exercise of
16 reasonable care, should have known that use of the APAP Products during pregnancy could
17 cause Plaintiffs' injuries, and thus, create a dangerous and unreasonable risk of injury to the
18 users of these products, including Plaintiffs.

19 94. As such, Defendants breached their duty of reasonable care and failed to exercise
20 ordinary care in the design, research, development, manufacture, testing, marketing, labeling,
21 supply, promotion, advertisement, packaging, sale, and distribution of the APAP Products, in
22 that Defendants manufactured and produced defective APAP Products, which carry the
23 significantly increased risk of causing neurodevelopmental disorders in children through
24 prenatal exposure to APAP; knew or had reason to know of the defects inherent in the APAP
25 Products; knew or had reason to know that a user's or consumer's use of the APAP Products
26 during pregnancy created a significant risk of harm and unreasonably dangerous side effects;
27 and failed to prevent or adequately warn of these risks and injuries.
28

1 95. Defendants had a duty to disclose the truth about the risks associated with
2 exposure to or use of APAP during pregnancy in its promotional efforts outside of the context
3 of labeling. Defendants were negligent in its promotion of APAP outside of the labeling
4 context by failing to disclose material risk information as part of its promotion and marketing of
5 the APAP Products, including through the internet, television, and print advertisements.

6 96. Despite Defendants' ability and means to investigate, study, and test the APAP
7 Products and to provide adequate warnings regarding use during pregnancy, Defendants failed
8 to do so. Indeed, Defendants wrongfully concealed information and further made false and/or
9 misleading statements concerning the safety and use of APAP.

10 97. Defendants' negligence included:

- 11 a. Manufacturing, producing, promoting, formulating, creating, developing,
12 designing, selling, and/or distributing the APAP Products while negligently
13 and/or intentionally concealing and failing to disclose the results of trials,
14 tests, and studies of APAP and the significantly increased risk of causing
15 neurodevelopmental disorders in children through prenatal exposure to
16 APAP, and, consequently, the risk of serious harm associated with human
17 use of APAP during pregnancy; and
- 18 b. Failing to undertake sufficient studies and conduct necessary tests to
19 determine whether or not the APAP Products were safe for its intended
20 consumer use and unborn children; and
- 21 c. Failing to provide adequate instructions, guidelines, and safety precautions to
22 those persons Defendants could reasonably foresee would use the APAP
23 Products during pregnancy; and
- 24 d. Failing to disclose to Plaintiff Mother, users, consumers, and the general
25 public that use of APAP during pregnancy presents severe risks of
26 neurodevelopmental disorders in children exposed to APAP prenatally; and
- 27 e. Failing to warn Plaintiff Mother, users, consumers, and the general public
28 that the APAP Products' risk of harm was unreasonable and that there were

1 safer and effective alternative medications or treatments available to Plaintiff
2 Mother and other users and/or consumers; and

3 f. Representing that the APAP Products were safe for their intended purposes
4 for pregnant women when, in fact, Defendants knew or should have known
5 the APAP Products were not safe for their intended purposes; and

6 g. Declining to make or propose any changes to the APAP Products' labeling or
7 other promotional materials that would alert users, consumers, and the
8 general public of the risks of APAP, including to pregnant women; and

9 h. Advertising, marketing, and recommending the use of the APAP Products
10 during pregnancy, while concealing and failing to disclose or warn of the
11 dangers known by Defendants to be caused by the use of or exposure to
12 APAP; and

13 i. Continuing to disseminate information to its consumers and the general
14 public, which indicates or implies that the APAP Products are not unsafe for
15 pregnant consumer use; and

16 j. Continuing the manufacture and sale of the APAP Products with the
17 knowledge that the APAP Products were unreasonably unsafe and dangerous.

18 98. Defendants knew and/or should have known that it was foreseeable that children
19 such as Plaintiff Child would suffer injuries as a result of Defendants' failure to exercise
20 ordinary care in the manufacturing, marketing, labeling, distribution, and sale of the APAP
21 Products to pregnant consumers, like Plaintiff Mother.

22 99. Plaintiff Mother did not know the nature and extent of the injuries that could
23 result in her child from the intended use of and/or exposure to APAP prenatally.

24 100. Defendants' negligence was a proximate cause of Plaintiffs' injuries, i.e., absent
25 Defendants' negligence, Plaintiff Child would not have developed ASD. That negligence was a
26 substantial factor in causing Plaintiffs' injuries and damages.

27 101. Defendants' conduct, as described above, was reckless. Defendants regularly
28 risked exposing Plaintiff Mother to the APAP Products while pregnant with Plaintiff Child, with

1 full knowledge of the dangers of the APAP Products and that it could cause ASD in Plaintiff
 2 Child. Defendants made conscious decisions not to redesign, re-label, warn, or inform the
 3 unsuspecting public, including Plaintiff Mother. Defendants' reckless conduct therefore
 4 warrants an award of punitive damages.

5 102. As a direct and proximate result of Defendants placing the defective APAP
 6 Products into the stream of commerce, Plaintiffs have suffered permanent injuries, significant
 7 pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality
 8 of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

9 10 **COUNT III: BREACH OF EXPRESS WARRANTY**

11 103. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
 12 set forth in the rest of this Complaint as if fully set forth herein.

13 104. At all material times, Defendants manufactured, marketed, sold, distributed, and
 14 otherwise placed into the stream of commerce the APAP Products. These actions were under
 15 the ultimate control and supervision of Defendants.

16 105. In advertising, marketing, and promoting the APAP Products to consumers, like
 17 Plaintiff Mother, Defendants expressly warranted that the APAP Products were safe for use and
 18 reasonably fit for their intended purposes, including use by pregnant mothers. In advertising,
 19 marketing, and otherwise promoting the APAP Products, Defendants intended for pregnant
 20 consumers to rely upon its representations regarding safety and fitness, in an effort to induce
 21 them to purchase and consume the APAP Products during pregnancy to relieve pain.

22 106. Defendants expressly warranted to Plaintiff Mother and pregnant consumers that
 23 the APAP Products were safe for ingestion during pregnancy.

24 107. Defendants had a duty to exercise reasonable care in the research, development,
 25 design, testing, packaging, manufacture, inspection, labeling, distributing, marketing,
 26 promotion, sale, and release of the APAP Products, including a duty to:

- 27 a. ensure that the APAP Products during pregnancy did not cause users and
 28 their unborn children unreasonably dangerous side effects; and

- b. warn of dangerous and potentially incurable side effects; and
- c. disclose adverse material facts, such as the true risks associated with the use of and exposure to APAP during pregnancy, when making representations to users, consumers, and the general public, including Plaintiff Mother.

108. Defendants had the ability to properly disclose the risks associated with APAP usage during pregnancy through multiple channels, not just labeling.

109. At all relevant times, Defendants expressly represented and warranted to the purchasers of the APAP Products, by and through statements made by Defendants in labels, publications, brochures, and other written materials intended for consumers and the general public, that the APAP Products were safe to human health and the environment, effective, fit, and proper for their intended use during pregnancy. Defendants advertised, labeled, marketed, and promoted the APAP Products, representing the quality to consumers and the public in such a way as to induce their purchases or use during pregnancy, thereby making an express warranty that the APAP Products would conform to the representations.

110. The representations about the APAP Products, as set forth herein, contained, or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

111. Defendants breached express representations and warranties made to Plaintiff Mother, with respect to the APAP Products, including the following:

- a. Defendants represented through their labeling, advertising, and marketing materials that the APAP Products were safe for use during pregnancy, and intentionally withheld and concealed information about the risks of serious injury associated with use of APAP and by expressly limiting the risks associated with use during pregnancy within its warnings and labels; and
- b. Defendants represented that the APAP Products were safe for use and intentionally concealed information that demonstrated that APAP carries the significantly increased risk of causing neurodevelopmental disorders in

1 children through prenatal exposure to APAP, and that the APAP Products,
2 therefore, were not safer than alternatives available on the market.

3 112. Plaintiff Mother detrimentally relied on the express warranties and
4 representations of Defendants concerning the safety and/or risk profile of APAP during
5 pregnancy in deciding to purchase the APAP Products. Plaintiff Mother reasonably relied upon
6 Defendants to disclose known defects, risks, dangers, and side effects of APAP. Plaintiff
7 Mother would not have purchased or used the APAP Products during pregnancy had
8 Defendants properly disclosed the risks associated with the APAP Products, either through
9 advertising, labeling, or any other form of disclosure. Defendants' breach of the express
10 warranties and representations concerning the safety and/or risk profile of APAP during
11 pregnancy was a substantial factor in causing Plaintiffs' injuries and damages.

12 113. Plaintiff Mother had no knowledge of the falsity or incompleteness of
13 Defendants' statements and representations concerning the APAP Products and could not have
14 taken reasonable steps to notify Defendants of those matters or to seek repair or other remedies.

15 114. Plaintiff Mother used and/or was exposed to APAP during pregnancy as
16 researched, developed, designed, tested, manufactured, inspected, labeled, distributed,
17 packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by
18 Defendants.

19 115. Had the warnings, labels, advertisements, or promotional material for the APAP
20 Products accurately and adequately set forth the true risks associated with the use of such
21 Products during pregnancy, including Plaintiffs' injuries, rather than expressly excluding such
22 information, and warranting that the APAP Products were safe for their intended use, Plaintiffs
23 could have avoided the injuries complained of herein.

24 116. As a direct and proximate result of Defendants' breach of express warranty,
25 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress,
26 lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all
27 damages to which they may be legally entitled.
28

COUNT IV: BREACH OF IMPLIED WARRANTY

117. Plaintiffs restate, reallege, and incorporate by reference each of the allegations set forth in the rest of this Complaint as if fully set forth herein.

118. At all material times, Defendants manufactured, marketed, sold, distributed, and otherwise placed the APAP Products into the stream of commerce.

119. At all material times, Defendants intended for the APAP Products to be consumed and ingested by pregnant women, like Plaintiff Mother; and Defendants impliedly warranted that the APAP Products and their component parts were of merchantable quality, safe, fit for such use, and adequately tested.

120. Defendants was aware that consumers, including Plaintiff Mother, would consume and ingest the APAP Products as directed by the Products' labels and promotional materials. Therefore, Plaintiff Mother was a foreseeable user of the APAP Products.

121. But Defendants failed to disclose that APAP has dangerous propensities when used as intended during pregnancy and that use of the APAP Products carries an increased risk of developing severe injuries, including Plaintiff Child's injuries.

122. The APAP Products were expected to reach, and did in fact reach consumers, including Plaintiff Mother, without substantial change in the condition in which they were manufactured and sold by Defendants.

123. Plaintiff Mother was an intended beneficiary of the implied warranties made by Defendants to purchasers of the APAP Products, including Plaintiff Mother.

124. In reliance upon Defendants' implied warranties, Plaintiff Mother purchased and used the APAP Products as indicated, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants. The failure of the APAP Products to be of merchantable quality, to be safe or fit for their intended use, or to be adequately tested was a substantial factor in causing Plaintiffs' injuries and damages.

125. Defendants breached their implied warranties to Plaintiffs in that the APAP Products were not of merchantable quality, nor were they safe or fit for their intended use or adequately tested.

126. The harm caused by the APAP Products far outweighed their benefit, rendering the APAP Products more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

127. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT V: VIOLATION OF CONSUMER PROTECTION LAWS

128. Plaintiffs restate, reallege, and incorporate by reference each of the allegations set forth in the rest of this Complaint as if fully set forth herein.

129. Plaintiff Mother purchased and used the APAP Products for primarily personal use and pain relief during pregnancy, thereby suffering ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

130. Had Defendants not engaged in the deceptive conduct described in this Complaint, Plaintiff would not have purchased and/or paid for the APAP Products, and Plaintiffs would not have incurred related injury medical costs.

131. Defendants engaged in wrongful conduct and unlawful while at the same time obtaining under false pretenses moneys from Plaintiff for the APAP Products. Those moneys would not have been paid had Defendants not engaged in unfair and deceptive conduct. Plaintiffs actually relied upon Defendants' misrepresentations and deception concerning the APAP Products.

132. Defendants engaged in the following unfair methods of competition or deceptive acts or practices, which are proscribed by law:

- A. representing that goods or services have characteristics, ingredients, uses, benefits, or qualities they do not have; and
- B. advertising goods or services with the intent not to sell them as advertised; and

1 C. engaging in fraudulent or deceptive conduct creating a likelihood
2 of confusion or misunderstanding.

3 133. Plaintiffs were injured by the cumulative nature of Defendants's conduct. The
4 cumulative effect, directed at patients, physicians, and consumers, was to create demand for and
5 sell the APAP Products. Each aspect of Defendants' conduct combined to artificially create
6 sales of the APAP Products, including to Plaintiff Mother who did, in fact, purchase the APAP
7 Products.

8 134. Defendants had a statutory duty to refrain from unfair or deceptive acts or trade
9 practices in the design, labeling, development, manufacture, promotion, and sale of the APAP
10 Products.

11 135. Defendants' deceptive, unconscionable, or fraudulent representations and
12 material omissions to consumers, including Plaintiff Mother, constitute unfair and deceptive
13 acts and trade practices in violation of the federal and state consumer protection statutes listed
14 below.

15 136. Defendants' actions, as complained of in this Complaint, constitute unfair
16 competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in
17 violation of the federal and state consumer protection statutes listed below.

18 137. Defendants has engaged in unfair competition, or unfair or deceptive acts or
19 trade practices, or has made false representations under the following statutes:

- 20 • 15 U.S.C. §§ 2301–12 (1982);
- 21 • Cal. Bus. & Prof. Code § 17200, et seq.;
- 22 • Cal. Civ. Code § 1750 et seq.

23 138. To protect consumers against unfair, deceptive, fraudulent, and unconscionable
24 trade and business practices, and false advertising, Defendants, as the supplier, manufacturer,
25 advertiser, and seller, is subject to liability under the above legislation enacted against unfair,
26 deceptive, fraudulent, and unconscionable consumer sales practices. The California Unfair
27 Competition Law ("UCL") prohibits "any unlawful, unfair, or fraudulent business act or
28 practice and unfair, deceptive, untrue, or misleading advertising and any act prohibited by"

1 Section 17500 of the California Business and Professions Code. Section 17500, in turn,
2 prohibits any untrue or misleading statements made in connection with the sale of goods. The
3 Consumers Legal Remedies Act (“CLRA”) defines as statutorily unlawful certain unfair
4 methods of competition and unfair or deceptive practices. Cal. Civ. Code § 1750 et seq.

5 139. By knowingly and falsely representing that the APAP Products were fit to be
6 used for the purposes for which they were intended—when in fact they were defective and
7 dangerous when used during pregnancy—and by other acts alleged, Defendants violated the
8 above statutes, enacted to protect consumers against unfair, deceptive, fraudulent, and
9 unconscionable trade and business practices, and false advertising.

10 140. Defendants’ actions and omissions are uncured or incurable, deceptive acts under
11 the above legislation.

12 141. Defendants had actual knowledge of the defective and dangerous conditions of
13 the APAP products but failed to take any action to cure such defective and dangerous
14 conditions.

15 142. Plaintiff Mother relied upon Defendants’ misrepresentations and omissions in
16 determining which APAP Products (if any) to ingest.

17 143. Defendants’ deceptive, unconscionable, or fraudulent representations and
18 material omissions to consumers constituted unfair and deceptive acts and practices.

19 144. By reason of the unlawful acts in which Defendants engaged, and as a direct and
20 proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

21 145. As a direct and proximate result of Defendants’ violations of the above-listed
22 legislation, Plaintiffs have sustained economic losses and other damages and are entitled to
23 statutory and compensatory damages, including restitution, in an amount to be proven at trial
24 and civil penalties as permitted by law.

25 **COUNT VI: NEGLIGENT MISREPRESENTATION**

26 146. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
27 set forth in the rest of this Complaint as if fully set forth herein.
28

1 147. Defendants had a duty to accurately and truthfully represent to consumers,
2 including to Plaintiff Mother and to the public, that the APAP Products had not been adequately
3 tested and found to be a safe and effective treatment for pregnant women. Defendants breached
4 that duty as their representations of the safety of the APAP Products were false. Defendants
5 intended for consumers like Plaintiff Mother to rely upon that representation, Plaintiff Mother
6 did justifiably rely on Defendants' misrepresentations concerning the APAP Products' high risk
7 of unreasonable and dangerous adverse side effects when ingested or used during pregnancy.

8 148. Defendants failed to exercise ordinary care in the representations concerning the
9 APAP Products while Defendants were involved in the manufacture, sale, testing, quality
10 assurance, quality control, and distribution in interstate commerce, because Defendants
11 negligently misrepresented the APAP Products' high risk of unreasonable and dangerous
12 adverse side effects when ingested or used during pregnancy.

13 149. Defendants also breached their duty in representing to Plaintiff Mother that the
14 APAP Products had no serious side effects when ingested during pregnancy. Defendants
15 intended for consumers like Plaintiff Mother to rely upon that representation, and Plaintiff
16 Mother did justifiably rely upon that representation.

17 150. Defendants knew or had reason to know that the APAP Products had been
18 insufficiently tested or had not been tested at all; and that they lacked adequate and accurate
19 warnings, and created a high risk, or a higher than acceptable reported and represented risk, of
20 adverse side effects. Those side effects include neurodevelopmental disorders in children, such
21 as ASD and ADHD. Thus, Defendants lacked reasonable ground for believing the
22 representations to be true and intended for consumers like Plaintiff to rely upon those
23 misrepresentations by purchasing the APAP products for use during pregnancy. Plaintiff
24 Mother justifiably relied upon those misrepresentations in purchasing and using the APAP
25 products while pregnant. Defendants's negligent misrepresentations concerning the safety
26 and/or risk profile of using APAP during pregnancy was a substantial factor in causing
27 Plaintiffs' injuries and damages.
28

1 cure the conditions proximately related to the use of the APAP Products, as well as the other
2 permanent and lasting severe personal injuries.

3 158. Defendants knowingly withheld material information from consumers and the
4 public, including Plaintiff Mother, concerning the safety and efficacy of the APAP Products
5 during pregnancy, which deprived Plaintiff Mother of vitally necessary information with which
6 to make a fully informed decision about whether to use the APAP Products while pregnant.

7 159. At all material times, Defendants also knew and recklessly and/or intentionally
8 disregarded the fact that the APAP Products, when used during pregnancy, can cause
9 debilitating and life-altering side effects with greater frequency than safer alternative methods,
10 products, and/or treatments. But Defendants recklessly failed to advise the medical community
11 and the general public, including Plaintiff Mother, of that fact.

12 160. At all material times, Defendants intentionally misstated and misrepresented
13 data; and Defendants continue to misrepresent data so as to minimize the perceived risk of
14 injuries and the rate of complications caused by or associated with the APAP Products.

15 161. Notwithstanding the foregoing and the growing body of knowledge and
16 information regarding the true and defective nature of the APAP Products, with their increased
17 risk of side effects and serious complications, Defendants continue to aggressively market the
18 APAP Products to consumers, including the pregnant community at large, without disclosing
19 the true risk of the complications and side effects.

20 162. When Plaintiff Mother consumed the APAP Products and since then, Defendants
21 have known the APAP Products were defective and unreasonably dangerous without an
22 adequate warning. But Defendants continued to manufacture, produce, assemble, market,
23 distribute, and sell the APAP Products to the pregnant community so as to maximize sales and
24 profits at the expense of the health and safety of expecting mothers in a conscious, reckless,
25 and/or intentional disregard of the likely and foreseeable harm caused by the APAP Products to
26 members of the public, including Plaintiffs.

27 163. At all material times, Defendants has concealed and/or failed to disclose to the
28 public the serious risks and the potential complications associated with the APAP Products, so

as to ensure continued and increased sales and profits and to the detriment of the public, including Plaintiffs.

164. Defendants' acts and omissions are of such character and nature so as to entitle Plaintiffs to an award of punitive damages in accordance with applicable statutory and common law. Defendants' conduct shows malice, oppression, or fraud, or that entire want of care, raising the presumption of conscious indifference to consequences of that conduct, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants individually, and jointly and severally. Plaintiffs also request compensatory damages, punitive damages, or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiffs demand judgment against Defendants, individually, and jointly and severally, and prays for the following relief in accordance with applicable law and equity:

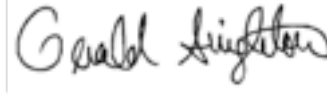
- i. Compensatory damages to Plaintiffs for past, present, and future damages, including pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law; and
- ii. Restitution and disgorgement of Defendants's profits; and
- iii. Punitive or enhanced compensatory damages; and
- iv. Reasonable attorneys' fees as provided by law; and
- v. Past and future costs of all proceedings; and
- vi. All ascertainable economic damages; and
- vii. Prejudgment interest on all damages as allowed by law; and
- viii. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demands a trial by jury on all issues so triable.

Dated: July 27, 2022

Respectfully submitted,



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